UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte KENNETH F. BUECHLER, and
PAUL H. MCPHERSON

Appeal No. 2004-2149
Application No. 09/687,051

ON BRIEF

Before MILLS, GRIMES, and GREEN, Administrative Patent Judges.

GREEN, Administrative Patent Judge.

DECISION ON APPEAL

An oral hearing in this case was scheduled for January 13, 2005. Upon reviewing the case, however, we have determined that an oral hearing will not be necessary and we render the following decision based on the record. See 37 CFR § 41.47(f). Note that this appeal is related to Appeal No. 2004-2387, Application Serial No. 09/349,194, and is decided concurrently therewith.

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 69, 70, 79-83, 86-89, 91 and 92.[1] Claim 69 and 71 are representative of the subject matter on appeal, and reads as follows:

> 69. An antibody or a fragment thereof, immobilized on a solid phase, that specifically binds cardiac troponin I, wherein said antibody is insensitive with respect to each form of cardiac troponin I selected from the group consisting of free cardiac troponin I, cardiac troponin I in a binary complex with troponin C, and cardiac troponin in a ternary complex with troponin C and troponin T.
>
> 71. A method of selecting antibodies for an immunoassay for cardiac troponin I, the method comprising:
>
> selecting two or more antibodies that, when used in said immunoassay, provide an assay response that is insensitive with respect to each form of cardiac troponin I selected from the group consisting of free cardiac troponin I, cardiac troponin I in a binary complex with troponin C, and cardiac troponin I in a ternary complex with troponin C and troponin T.

No prior art is relied upon by the examiner in the rejection of the claims on appeal.

Claims 69, 70, 79-83, 86-89, 91 and 92, stand rejected under 35 U.S.C. § 112, first paragraph, on the grounds that the specification fails to enable the full scope of the claimed invention. After careful review of the record and consideration of the issues before us, we reverse.

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[1] The examiner has indicated that claims 71-74 are allowable as written, and claims 84, 85, 90 and 93 would be allowable if written in independent form. See Appeal Brief, page 4.

DISCUSSION

Claims 69, 70, 79-83, 86-89, 91 and 92 stand rejected under 35 U.S.C. § 112, first paragraph, on the grounds that

> the specification, while being enabl[ing] for a cocktail of insensitive antibodies, wherein each antibody binds each one of the free cTnI, binary complex of cTnI, and ternary complex of cTnI for use in an assay for determining free and complexed cardiac specific isoforms of troponin (cTnI), does not reasonably provide enablement for a single insensitive antibody, which binds each one and all of free cTnI, binary complex of cTnI, and ternary complex of cTnI for use in an assay for determining free and complexed cTnI. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Examiner's Answer, pages 3-4.

The rejection then looks at each of the Wands factors. See In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1403 (Fed. Cir. 1988). The factors discussed by the court in Wands include: (1) the quantity of experimentation necessary to practice the invention, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

As to the nature of the invention, the examiner asserts that "the invention is directed to insensitive antibodies which bind each one of the free, binary complex, and ternary complex isoforms of cTnI for use in a method for determining the presence or amount of each and all of free, binary and ternary

complexed isoforms of cTnI." Examiner's Answer, page 4. As to the state of the prior art, the examiner contends that the prior art "fails to disclose an insensitive antibody which binds each and all of the free, binary and ternary complexed isoforms of cTnI." Id. at 5.

With respect to the predictability or lack thereof in the art, the rejection focuses on the specification, stating that "there is no predictability based on the instant specification that a single insensitive antibody binds each and all of the free, binary and ternary complexed isoforms of cTnI for use in a method of determining the presence or amount of all of the free, binary and ternary complexed isoforms of cTnI in a sample." Id. As to the amount of direction or guidance present, and the presence or absence of working examples, the rejection focuses on the lack of a working example using an insensitive antibody that specifically binds each of the free, binary and ternary complexed forms of cTnI. See id. at 5-6. The rejection acknowledges that the level of skill in the art is high, but asserts that it would require an undue amount of experimentation to make and use the method as claimed. See id. at 6.

Finally, the rejection focuses on the breadth of the claims. The rejection acknowledges that

> [a]t pages 21-22, the specification shows how to generate and select antibodies that are sensitive[2] or insensitive[3] to the binding of

[2] The specification defines a sensitive antibody as an antibody that will tend to bind only a single form of troponin. See Specification, page 6.

[3] The specification defines an insensitive antibody as an antibody that will tend to bind more than one form of troponin, i.e., oxidized and reduced forms of the troponin, or free or complexed forms of troponin. See Specification, page 6.

> free troponin I or T, troponin I or T in binary complexes, and troponin I or T in ternary I/T/C complexes; this is accomplished by purification of free troponin I or T, binary troponin I/T, T/C, and I/C complexes and ternary I/T/C complexes, respectively, then injection into mice or rabbits to generate monoclonal or polyclonal antibodies. The antibodies are then screened for affinity and specificity with the purified free troponin, binary complexes of troponin, and ternary complexes of troponin.

Id. at 7.

The rejection then goes on to argue, however, that the specification only exemplifies the use of a cocktail of antibodies that can bind to free cTnI, binary complexed cTnI and ternary complexed cTnI, and does not provide a working example using an single, insensitive antibody that can bind to all of the forms of cTnI. The rejection asserts that "[t]he fact that insensitive antibodies that bind more than one form of cTn has [sic] been characterized, is not sufficient to enable the breadth of the claimed method to use a single insensitive antibody in an assay to determine the presence or amount of all of free cTnI, binary complexed cTnI, and ternary complexed cTnI." Id. at 7.

Appellants argue that the rejection is based upon the "unsupported assertion that, while the specification is enabling with regard to a pool of antibodies that are insensitive for (binds to) each of free troponin I, troponin I in binary complexes with troponin C, and troponin I in ternary complexes with troponin C and troponin T, the specification is not enabling with regard to a single antibody that binds each of the recited cardiac troponin I forms." Appeal Brief, pages 9-10 (emphasis in original). We agree.

"[A] specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971) (emphasis in original). "[It] is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement." Id. at 224, 169 USPQ at 370. Here, the examiner has not provided "acceptable evidence or reasoning which is inconsistent" with the specification, and therefore has not met the initial burden of showing nonenablement.

The rejection is primarily premised on the fact that the specification fails to provide a working example of an insensitive antibody that binds each of free and complexed cTnI. The rejection, however, provides no evidence to support the assertion that it would require an undue amount of experimentation to generate and screen for antibodies that can bind to the free and binary and ternary complexed forms of cTnI, and the rejection is reversed.

As acknowledged by the rejection, the specification shows how to generate and select antibodies that are sensitive or insensitive to the binding of

free troponin I or T, troponin I or T in binary complexes, and troponin I or T in ternary I/T/C complexes. See Examiner's Answer, pages 6-7; see also, Specification, pages 21-24. Moreover, as noted by appellants, see Appeal Brief, pages 12-13, the specification states that while the immunoassay may be formulated using a cocktail of antibodies, it may also be formulated "with specific antibodies that recognize epitopes of the troponin I and T in the complexes and also the unbound troponin I and T." Specification, page 24. Example 23 of the specification demonstrates the selection of an antibody that binds to both free troponin I and troponin I in a ternary complex. See id. at 88.

The specification thus teaches the skilled artisan how to generate and screen for antibodies having the desired binding specificity. The fact that appellants failed to provide a working example of an antibody that binds to free cTnI, as well as binary and ternary complexed cTnI is not in and of itself dispositive on the issue of whether the specification enables such an antibody given the lack of evidence on the part of the rejection demonstrating why one skilled in the art would not expect to be able to produce such an antibody.

OTHER ISSUES

We note that appellants submitted an article of Giuliani et al., "Determination of Cardiac Troponin I Forms in the Blood of Patients with Acute Myocardial Infarction and Patients Receiving Crystalloid or Cold Blood Cardioplegia," Clinical Chemistry, Vol. 45, pp. 213-222 (1999), to support their position that "[a] method of making even a single monoclonal antibody that binds

to all forms (free, binary and ternary of cTnI) is feasible without undue experimentation." Communication to the Examiner dated September 25, 2003, page 3. Our review of the record however, does not reveal whether the examiner ever considered the article, and it is thus unclear if the article is part of the record on appeal. In view of our disposition of the appeal, we see no need to remand the application at this time for clarification, but the examiner should in the future clearly indicate on the record whether such evidence has been considered and made of record.

CONCLUSION

Because the rejection under 35 U.S.C. § 112, first paragraph, on the grounds that the specification fails to enable the full scope of the claimed subject matter, fails to provide acceptable evidence or reasoning that is inconsistent with the specification, and thus fails to meet the initial burden of showing nonenablement. Therefore, the rejection is reversed.

REVERSED

Demetra J. Mills)
Administrative Patent Judge)
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Eric Grimes) BOARD OF PATENT
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) APPEALS AND
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